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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

AHMED, SHEEBA

ART UNIT	PAPER NUMBER
1773	

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/827,887	CLAUDE ET AL.
Examiner	Art Unit	
Sheeba Ahmed	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 21 January 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 33-41 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 33-41 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Response to Amendment***

1. Claims 1-32 have been cancelled in the above-identified application. New claims 33-41 have been added. **Claims 33-41 are now pending.**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 33-36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Trotta (US 5,620,649).

Trotta discloses balloon catheters wherein the balloon comprises a pair of first layers made of a flexible material and a second layer positioned between the first layers and comprises a vinylic polymer having functional groups chemically bonded to the first layers (***the first layers disclosed by Trotta correspond to the first and second layers of the claimed invention and the second layer disclosed by Trotta corresponds to the covalently bonded functionality of the claimed invention***)

(Column 2, lines 8-13). The functional groups, which are found on the vinylic polymers, include carboxylic acid (***thus meeting the limitations of claim 36***) (Column 2, lines 29-35). As is conventional, the balloon catheter comprises an inflation lumen (***which is an elongated shaft as seen in Figure 1 and thus meeting the limitations of claim 38***)

provided for fluid inflation and deflation of the balloon. The first layers may be formed of nylon and the second (bonding) layer may be formed of a modified polyethylene resin having pendant carboxylic acid groups such that a covalent bond may be formed between the second layer and the first (outer) layers through the carboxylic acid groups (Column 4, lines 17-44). The determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see MPEP 2113. In this case, the product (i.e., the balloon catheter) is the same despite the process limitation of plasma polymerizing the functionalized layer. All limitations of claims 33-36 and 38 are disclosed in the above reference.

3. Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhong (US 6,048,620).

Zhong discloses balloon catheters for angioplasty (Column 1, lines 25-26) wherein at least the balloon part is provided with a coating comprising a polymer having organic acid functional groups and a crosslinking agent having functional groups capable of reacting with organic acid groups wherein the coating is applied, dried and then further coated with a hydrophilic polymer having organic acid functional groups such that the hydrophilic polymer becomes bonded to the polymer of the first coating composition through the crosslinking agent (***the balloon part disclosed by Zhong***

***corresponds to the second layer of the claimed invention, the first coating disclosed by Zhong corresponds to the covalently bonded functionality of the claimed invention and the second coating disclosed by Zhong corresponds to the first coating of the claimed invention)*** (Column 3, lines 15-30). Examples of organic acid groups include carboxylic acid groups (Column 4, lines 53-56). Examples of the first coating composition include acrylic copolymer dispersions (***thus meeting the limitations of claims 36 and 37)*** (Column 5, lines 30-33). The determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see MPEP 2113. In this case, the product (i.e., the balloon catheter) is the same despite the process limitation of plasma polymerizing the functionalized layer. All limitations of claims 33-37 are disclosed in the above reference.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (US 6,048,620).

Zhong, as discussed above, do not disclose that the covalently bonded or grafted functionality has a thickness of 10nm to 150nm. However, it would have been obvious to one having ordinary skill in the art to optimize the thickness of the covalently bonded functionality given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution.

5. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Zhong (US 6,048,620).

Trotta discloses balloon catheters wherein the balloon comprises a pair of first layers made of a flexible material and a second layer positioned between the first layers and comprises a vinylic polymer having functional groups chemically bonded to the first layers (***the first layers disclosed by Trotta correspond to the first and second layers of the claimed invention and the second layer disclosed by Trotta corresponds to the covalently bonded functionality of the claimed invention***) (Column 2, lines 8-13). The functional groups, which are found on the vinylic polymers, include carboxylic acid (Column 2, lines 29-35). As is conventional, the balloon catheter comprises an inflation lumen provided for fluid inflation and deflation of the balloon. The first layers may be formed of nylon and the second (bonding) layer may be formed of a modified polyethylene resin having pendant carboxylic acid groups such that a covalent bond may be formed between the second layer and the first (outer) layers through the carboxylic acid groups (Column 4, lines 17-44).

Trotta does not disclose that the first layer (which corresponds to the first layer of the claimed invention) is made of polytetrafluoroethylene.

However, Zhong teaches that the materials used to make a balloon catheter include polytetrafluoroethylene, nylons, PE, PP, PVC and other resins (Column 8, lines 44-55). Zhong shows that polytetrafluoroethylene and nylon are equivalent structures known in the art. Therefore, because these two resins were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute polytetrafluoroethylene for nylon.

6. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Okuda et al. (US 6,053,939).

Trotta discloses balloon catheters wherein the balloon comprises a pair of first layers made of a flexible material and a second layer positioned between the first layers and comprises a vinylic polymer having functional groups chemically bonded to the first layers (***the first layers disclosed by Trotta correspond to the first and second layers of the claimed invention and the second layer disclosed by Trotta corresponds to the covalently bonded functionality of the claimed invention***) (Column 2, lines 8-13). The functional groups, which are found on the vinylic polymers, include carboxylic acid (Column 2, lines 29-35). As is conventional, the balloon catheter comprises an inflation lumen provided for fluid inflation and deflation of the balloon. The first layers may be formed of nylon and the second (bonding) layer may be formed of a

modified polyethylene resin having pendant carboxylic acid groups such that a covalent bond may be formed between the second layer and the first (outer) layers through the carboxylic acid groups (Column 4, lines 17-44).

Trotta does not disclose that the first layer (which corresponds to the first layer of the claimed invention) has a node and fibril microstructure.

However, Okuda et al. teach that a material having a nodes and fibril microstructure has excellent biocompatibility (Column 1, lines 11-19).

Accordingly, it would have been obvious to one having ordinary skill in the art to replace the nylon outer layer disclosed by Trotta with a material having a nodes and fibril microstructure given that Okuda et al. specifically teach that such a microstructure provides excellent biocompatibility.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 33-41 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheeba Ahmed whose telephone number is (703)305-0594. The examiner can normally be reached on Mon-Fri 8am-4pm.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)306-5665.

*SA*  
Sheeba Ahmed  
April 2, 2003

*Paul Thibodeau*  
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